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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/265,606 | 03/10/1999 | RAINER ZIMMERMANN | LUD5330.3DIV | 4727 |

24972 7590 10/21/2002

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| EXAMINER |
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MORAN, MARJORIE A

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| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 10/21/2002

Q2

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/265,606

Applicant(s)

ZIMMERMANN ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-26 is/are pending in the application.
- 4a) Of the above claim(s) 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,21 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Remarks

In response to the request for an explanation of delay of an office action, the examiner again apologizes for the delay. The case was misplaced for a period of several weeks, thus occasioning the delay mentioned. The examiner thought she made this clear in an oral communication; as this conversation did not touch on the merits of the case, an Interview Summary making this conversation of record was not processed or mailed. The examiner regrets any confusion, and urges applicants to request an extension of patent term if they feel such is merited.

Election/Restrictions

Newly submitted claim 22 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: an isolated peptide consisting of SEQ ID NO: 4, 6, or 7 is a different structure (product) than a chimeric/fusion protein consisting of a catalytic domain and a portion of a non-FAP α protein, and would be expected to have different properties and to behave differently in methods of use. In addition, a search for a peptide consisting of any of SEQ ID 4, 6 or 7 would be a different search than the search for the chimeric/fusion protein of claims 20-21 and 23-26.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 22 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 20-26 are pending. An action on the merits of elected claims 20-21 and 23-26 follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-21 and 23-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

A protein consisting of a portion of a non-FAP α protein and "at least on catalytic domain of FAP α protein", wherein catalytic domain consists of one or more of SEQ ID NO's 4, 6, and 7, as recited in the new claims, is new matter. Original claim 5 recited a protein consisting of a portion of a non- FAP α protein and the FAP α catalytic domain. Original claims 8 and 11, directed to methods, recited use of a molecule comprising "an FAP α catalytic domain. Original claim 2 limited a FAP α protein to comprise SEQ ID NO: 2. None of the original claims recited a catalytic domain consisting of one or more of SEQ ID NO' 4, 6, and/or 7. As previously set forth and maintained by the examiner (see below), the originally filed specification does not describe "the catalytic domain" of FAP α . The originally filed specification discloses on page 21 that a fusion protein may comprise extracellular domains of both FAP α and murine CD8, but does not specifically define what those domains consist of. The originally filed specification also discloses on page 22 fusion proteins which contain the catalytic domain and portions of non-FAP α components, but does not define the catalytic domain per se. The originally filed specification discloses, on p. 13, Table 2, that putative catalytic domains of FAP α comprise SEQ

ID NO's 4, 6, and 7. As argued by applicant in the response filed 7/10/00, the ellipses of Table 2 indicate amino acids not specifically shown between those specifically provided, therefore it is clear that any catalytic domain MUST comprise amino acids other than SEQ ID NO's 4, 6, and 7. Further, it appears that the putative FAP α catalytic domain comprises ALL of SEQ ID NO's 4, 6, and 7. In summary, the disclosure of Table 2 of the originally filed specification does not provide support for a protein wherein a catalytic domain consists of SEQ ID NO's 4, 6, AND 7, nor for a catalytic domain consisting of any lesser combination thereof, nor for a catalytic domain consisting of only one of the recited SEQ ID NO's. The response filed with the amendment of 7/8/02 does not point to support in the originally filed claims or specification for the new limitations, and none is apparent, as set forth above, therefore the claims are rejected for reciting new matter.

Applicant's arguments filed 7/8/02 have been fully considered but they are not persuasive. Applicant argues that the specification teaches, in Table 2 and on page 12, three segments which are highly conserved in catalytic domains of related proteins. That the putative catalytic domain of FAP α comprises these conserved domains is not in question; the examiner agrees that Table 2 teaches conserved regions found within catalytic domains of the proteins shown. However, a teaching that a catalytic domain comprises conserved regions is not a full and complete description of the catalytic domain of FAP α . In response to applicant's argument that the catalytic domain "is contained within" amino acids 621-737, the examiner reiterates that this is not taught anywhere in the originally filed specification. That a conserved region begins at residue 621 is not a disclosure that the catalytic domain itself actually begins at that residue. Likewise, a conserved region ending at residue 737 is not a teaching that the catalytic domain itself ends at that residue. It is possible that the entirety of the catalytic domain extends beyond

residues 621 and 737; and the teaching of Table 2 for ellipses at either end of the conserved regions is a disclosure that the putative catalytic domain of FAP α does indeed do so. For these reasons, the examiner maintains that the originally filed specification does not fully and completely describe "the catalytic domain" of FAP α .

Conclusion

New claims 20-21 and 23-26 are rejected; claim 22 is withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

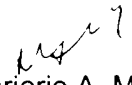
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for

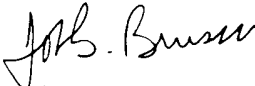
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the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Tina Plunkett, whose telephone number is (703) 305-3524.


Marjorie A. Moran
Examiner
Art Unit 1631

October 18, 2002


JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER